

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, drawn to a process for producing a taste-masked composition.

Group II, claim(s) 9-13, drawn to an active-containing ion exchange resin composition.

Group III, claim(s) 14-15, drawn to the method for improving an organoleptic property of a hydrogen form cation exchange resin loaded with an active compound.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical feature which is common to the three groups, namely an ionic active compound does not define a contribution over the prior art as evidenced by EP 117915 in Col. 4, lines 38-42 . Therefore the cited technical feature does not constitute a special technical feature and hence there is lack of unity between the cited groups.

3. During a telephone conversation with Frank Smith on August 25, 2009 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. The reference utilized in this rejection was cited in the International Search Report for PCT/EP2004/008394 to which applicant claims benefit. Also, the reference has been cited on the attached PTOL-892 for the sake of completeness of record.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1175915 (hereinafter '915).

7. Regarding claim 1, '915 teaches a method for the aqueous loading of water soluble and soluble pharmaceutically active substances onto ion exchange resins [0001]. The complex formed between a polymeric material and an active substance can be used in taste masking of bitter drugs, control of the site of administration of drugs, control of the release of flavor substances, and stabilization of unstable substances [0002]. The method for loading active substances into an ion exchange resin is to dissolve an acidic or basic, ionizable active substance in water, and then mix it with a suitable ion exchange resin. Also, '915 teaches a method for preparing a resinate comprising a blending a poorly water soluble or soluble active substance with an ion exchange resin and a solvent selected from the group consisting water, a water miscible solvent, a water-immiscible solvent or mixtures thereof to form an active substance/resin/solvent mixture [0020]. The water immiscible solvents used in the invention are hydrocarbons, halogenated hydrocarbons, ethers, ketones, and esters [0041].

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8. Regarding claim 2, '915 teaches AMBERLITE IRA67 which is a polymeric matrix that has a weak acidic cation exchange resins having carboxylic acid functional groups (Examples 1 and 2).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1175915 (hereinafter '915) in view of WO 01/70194 (hereinafter '194).

13. To further advance the prosecution of this invention, BESS et al. (U.S. Patent No. 7,067,116, hereinafter BESS), which is an English Equivalent of WO 01/70194 will be used in this rejection.

14. Regarding claims 3-6, '915 teaches a method for the aqueous loading of water soluble and soluble pharmaceutically active substances onto ion exchange resins [0001]. However, '915 does not teach a hexane, heptane, octane, isooctane, cyclopentane, cyclohexane, methyl cyclohexane, ethyl cyclohexane, carbon disulfide, trichloroethylene, carbon tetrachloride, benzene, toluene, xylene, propenol, butanol, butanone, and mixtures thereof used for washing the loaded matrix having a polarity of less than 5, 3, and 1.

15. In the same field of endeavor of masking the taste of pharmaceutically active agent, BESS teaches fast dissolving orally consumable films containing an agent to mask the taste of a pharmaceutically active agent which is dextromethorphan hydrobromide and diphenhydramine hydrochloride (Table A) to such as films containing an ion exchange resin as the taste masking agent. The taste-masking agent is an AMBERLITE IRP-69 resin (Col. 4, lines 43-44) and EUDRAGIT S can also be used a taste masked polymer which are coated with solvents such as hexane and toluene (Col. 11, lines 28-30). Even though BESS does not teach hexane as a nonpolar solvent used

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for washing the loaded matrix as a use in his composition, the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau*, 57 USPQ 324; *Ex parte Douros*, 163 USPQ 667; and *In re Craige*, 89 USPQ 393.

16. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to utilize hexane of BESS with the invention of '915 as a washing solvent for the benefit of obtaining a taste-masked active containing composition with a high active content and is substantially free of unbound active compounds since the process removes unbound active compounds without causing dissociation of bound active compounds.

17. Regarding claims 7-8, '915 teaches anionic exchange resins and cationic exchanges resins such as AMBERLITE IRA67 [0021, Examples 1 and 2]. However, '915 does not teach the polymeric matrix having anionic functional groups used is a hydrogen form cation and the active-loaded hydrogen from cation exchange resin obtained is further neutralized with a metal ion.

18. In the same field of endeavor of taste masking a pharmaceutically active agent, BESS teaches AMBERLITE IRP-69 (Col. 4, lines 60-62) which is a polymeric matrix that has strong acidic cation exchange resin having sulfonic acid functional groups and is neutralized by sodium ions.

19. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to utilize AMBERLITE IRP-69 of BESS for the benefit of taste-masking pharmaceutically active agents such as dextromethorphan hydrobromide.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEVE VALDEZ whose telephone number is (571)270-7738. The examiner can normally be reached on Mon-Thurs, 7:30pm-5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-2119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DEVE VALDEZ/

/Vasu Jagannathan/
Supervisory Patent Examiner, Art Unit 1796